

January 22, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

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RE: Docket No. 00D-1598

Dear FDA,

I am writing about your "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." I am deeply disappointed that the FDA continues to ignore the will of the public and refuses to make labeling of genetically engineered foods mandatory.

Your agency admits to receiving more than 50,000 comments last year regarding genetically engineered foods. You concede: "Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food." Yet you ignore the will of the public saying the comments "did not provide data or other information regarding consequences to consumers from eating the food." The truth is there has been ample evidence submitted to the FDA revealing that these foods are NOT "substantially equivalent" to non-genetically engineered foods. Yet your agency continues to ignore this evidence.

Studies have shown that biotech soybeans contain altered levels of nutrients such as isoflavones. They have been shown to have higher levels of Kunitz trypsin inhibitor, a known antinutrient and allergen. Genetically engineered foods contain antibiotic marker genes and many contain built-in pesticides. These are not found in non-genetically engineered foods. I do not want to eat these biotech foods, but without mandatory labeling I have no choice.

Last year, Monsanto admitted to finding "unexpected gene fragments" in their genetically engineered soybeans. What other "unexpected gene fragments" are contained in other genetically engineered foods? The truth is that the FDA does not know, because these experimental foods have not been adequately tested. New proteins never before consumed by humans are being created and brought to market without any extensive tests being done to show that they are not causing allergies, cancer or other diseases.

In the case of genetically engineered foods, the FDA has done a poor job of protecting the safety of consumers. Please remember that the potential allergies created by the ingestion of StarLink corn completely escaped the

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FDA regulatory guidelines. It was the EPA that discovered the digestive problems associated with StarLink corn.

The FDA has been accused of being a pawn of biotech industry. It is documents such as your Draft Guidance for Industry that leads many to feel this belief holds some truth. In your Draft Guidance you question whether manufacturers who choose not to use genetically engineered ingredients should be able to label their products as GMO Free. It is bad enough that the FDA does not require the mandatory labeling of genetically engineered foods. Now your agency even seems to be exploring the idea of restricting the ability of a manufacturer to let consumers know the products are not genetically engineered. Such regulatory restrictions would be an outrageous act of censorship by the FDA.

Genetically engineered foods are required to be labeled in the European Union nations, in Japan, Australia, New Zealand and other countries. Recently, both the E.U.-U.S. Biotechnology Consultative Forum and the Consumer Federation of America recommended mandatory labeling of genetically engineered foods. The FDA should stop working on behalf of the manufacturers of genetically engineered foods and begin to work for the safety and rights of the American public. I insist that genetically engineered foods be labeled!

Sincerely,

A handwritten signature in cursive script that reads "Michele M. Makrucki".

Mrs. Michele M. Makrucki
6 Streamview Court
Durham, NC 27713

PCRM GO VEGETARIAN!
Ms. Michele Makrucki
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